K040416

JUL 0 2 2004

510(k) SUMMARY

Name of 510(k) sponsor:	Philips Oral Healthcare, Inc.
Address:	35301 SE Center Street Snoqualmie, WA 98065 Telephone: 425 396-2000 Fax: 425 396-4825
Contact information:	Ms. Rose DeGiacomo Telephone: 425 396-2308 Fax: 425 396-4825
Date summary prepared:	February 18, 2004
Proprietary name of device:	Sonicare® Advance Toothbrush (Model 4900)
Generic/classification name:	Toothbrush, powered
Product code (classification):	JEQ (Class 1, 21 C.F.R. § 872.6865)

Legally Marketed Predicate Devices:

TX Electric Toothbrush (K921773)

Dental Air Force Home Dental Cleaning System (K001493)

Device Description and Technological Characteristics:

Sonicare® Advance Model 4900 consists of three primary parts: brush head, power handle, and charger base. Central to the brush head are the resonator arm and the torsion bar. The brush head's bristles are mounted in a bristle plate on one end of the arm, two magnets are mounted on the other, and the torsion bar is perpendicular in the middle. A 261-Hz oscillating magnetic flux generated inside the power handle forces the magnets into motion, which then causes the resonator arm to oscillate about the torsion bar. The torsion bar, magnets and bristle plate have a resonant frequency close to the 261-Hz driving frequency, and this enables the system to produce a desired amplitude effect. The bristles vibrate in the direction perpendicular to the bristles' length and nominally perpendicular to the brush's axis.

The oscillating magnetic flux is generated by a stator coil in the power handle, in close proximity to the attachment of the brush head. The flux is controlled by solid-state electronics and powered from two nickel-cadmium rechargeable batteries elsewhere within the handle. Energy for recharging the batteries is transferred from the charger base through a system of induction

coils within the power handle and the charger base. Maximum power dissipation by the handle is 3 W.

The charger base runs on standard North American 120 V, 60 Hz power. Internal electronics convert the input power to a 65 kHz output signal for more efficient transfer of power to the handle.

Intended Use

For promotion of good oral hygiene, including the reduction of dental plaque and gingivitis.

Testing

Various models of the Sonicare® Advance toothbrushes (identical or closely similar in specifications to the Model 4900) have been studied in a total of seven clinical trials (six controlled). Endpoints evaluated in these trials include examination of soft tissues for evidence of injury and indices of gingival inflammation (six trials), as well as pocket probing depth and clinical attachment level (four trials). Collectively, the studies demonstrate that the Sonicare® Advance toothbrushes reduce gingivitis.

Conclusions

The results from these tests support the safety and effectiveness of the 4900 model of the Sonicare® Advance toothbrush and its substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 2 2004

Ms. Rose DeGiacomo
Corporate Counsel
Philips Oral Healthcare
35301 S.E. Center Street
Snoqualmie, Washington 98065

Re: K040416
Trade/Device Name: Sonicare® Advanced Toothbrush (Model 4900)
Regulation Number: 872.6865
Regulation Name: Powered Toothbrush
Regulatory Class: I
Product Code: JEQ
Dated: June 14, 2004
Received: June 18, 2004

Dear Ms. DeGiacomo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040416

INDICATIONS FOR USE STATEMENT

Applicant: Philips Oral Healthcare, Inc.

510(k) Number: K040416

Device Name: Sonicare® Advanced Toothbrush (Model 4900)

Indications for Use:

For promotion of good oral hygiene, including the reduction of dental plaque and gingivitis.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ or Over-the Counter Use ✓

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040416